

REMARKS

The specification has been amended to correct typographical errors on pages 29 and 30 with respect to the dimensions of Examples 2 and 3 of the sterilization bag of the invention. Support for these revisions is present in the first paragraph of page 29, which states that

“A gas-permeable substrate 12 made of sterilization paper and having a width of 70mm, a height of 350mm and a weight of 70g/m², and a synthetic resin film 14 having the same measurements as those of the gas-permeable substrate 12 and composed of a biaxially oriented PET film having a thickness of 12μm and a PP film having a thickness of 30μm were used.” (Emphasis added.)

The rejection of the claims under 35 USC §102(b) and 103 has been obviated by amending the claims to more clearly define the invention over the art of record. However, before the specific language of the amendment is discussed, a brief recap of the principal features and advantages of the invention will be made so that the language of the amendment may be more fully appreciated.

As set forth in the “Background...” section of the application, sterile bags for holding surgical instruments are known in the art. Such bags generally comprised a rectangular synthetic sheet adhered around three of its edge portions to a gas permeable sheet to leave an open end at the upper portion of the bag. However the applicant has observed that the tips of the instruments stored in such bags can de-laminate or otherwise damage the bag at the adhered portions when such bags are supported in an upright position, as set forth in the first full paragraph of page 2 as follows:

As mentioned above, sterilization bags generally have two films that are heat sealed so as to be peelable. For this reason, when these types of medical instruments are stored in the sterilization bag, or when, after sterilization, the bag is disposed in the forceps stand, the tip portions of the medical instruments contact the heat-sealed portion of the lower end of the sterilization bag. There have been problems where the heat-sealed portion thus peels and opens. Further, when heat sterilizing such as autoclave sterilization (AC sterilization) is performed for a sterilization bag in which one of base materials serving as a gas-permeable substrate is paper and in

which the other is a synthetic resin film, there is a tendency for only the synthetic resin film to shrink and curl, making it easier for the tip portions of the medical instruments to contact the paper substrate in the lower end of the sterilization bag. There has thus been a tendency for the paper substrate to be damaged.

The invention advantageously prevents such damage by preventing the tips of surgical instruments from coming to rest on the adhered portions of the bag when the bag is placed into an upright position. To this end, the invention provides a damage prevention means including a protective synthetic resin sheet that defines a substantially straight lower end portion that catches the tips of stored articles and prevents the tips from engaging adhered portions between said gas-permeable material and said synthetic resin film when said bag when oriented in an upright position. The synthetic resin sheet may be formed from a mountain fold in the same resin film that forms a side of the bag, such as illustrated in the embodiments of the invention in Figures 1A, B and 3A, B. Alternatively, the synthetic resin sheet may be a separate sheet that forms the bottom, tip-receiving surface of the bag when it is oriented upright, such as shown in the embodiments of the invention illustrated in Figures 6A, B; 7A, B; and 9A-11.

The claims have been amended to more clearly recite the structural features responsible for the advantages of the invention. Specifically, claim 1 has been revised to recite a sterilization bag wherein side edges and lower ends of a gas-permeable material and a synthetic resin film are adhered with an opening remaining in an upper end thereof comprising a damage prevention means that prevents damage of at least one selected from the gas-permeable material, the synthetic resin film and an adhered portion of the gas-permeable material and the synthetic resin film by catching or receiving the tips of stored articles in the lower end portion of the sterilization bag or vicinity thereof,

wherein the damage prevention means is a protective component disposed in the inner surface of the lower end portion of the sterilization bag or the vicinity thereof, the upper end of the protective component being fixed to at least the gas permeable material, and the damage prevention means prevents the damage by catching the tip of stored articles.

Support for this amendment is present in initially filed claim 7 and on page 20, lines 12-17 and in Figures 5-11.

None of the references of record either discloses or suggests the sterile bag defined in amended claim 1. All that the Ota '518 Japanese patent document discloses is a bag for sterilization having opposing sides comprising a side front film 11 and a gas permeable sheet 12, and a bottom film 10 that is folded and heat sealed along its side edges 13 to the side edges of the film 11 and sheet 12 to form a boat-shaped bottom (see Figures 2, 4 and 6, and paragraph [0021]. There is no damage-preventing component or structure whatever at the boat-shaped bottom; hence the adhesive joints between the gas permeable sheet 12 and the bottom film 10 are vulnerable to being de-laminated by the tips of surgical instruments stored in the bag, particularly when the bag is oriented into an upright position. Accordingly this reference neither discloses nor suggests the recited damage prevention means formed by a

protective component disposed in the inner surface of the lower end portion of the sterilization bag or the vicinity thereof, the upper end of the protective component being fixed to at least the gas permeable material, and the damage prevention means prevents the damage by catching the tip of stored articles.

Nor are these features remotely suggested by the prior art bag illustrated in Figure 7 of the Ota '518 patent. The Figure 7 bag is formed from only two side sheets of plastic and paper, respectively, as is described in paragraph [0003]. There is no "damage prevention means", let alone the specifically recited damage prevention means that is a protective component disposed in the inner surface of the lower end portion of the sterilization bag or the vicinity thereof, and having an upper end "fixed to at least the gas permeable material" that prevents damage by catching the tip of stored articles. For all of these reasons, amended claim 1 is patentable over the Ota '518 patent.

Claims 2-6 have been cancelled, and hence no further discussion is deemed necessary.

Claim 7 has been cancelled since the limitation therein has been substantially incorporated into amended claim 1.

Claims 8 and 9 are patentable at least by reason of their dependency on amended claim 1.


Claim 10 is patentable not only for its dependency on amended claim 1, but for its recitation that “the protective component is a bag component formed by mountain folding a third synthetic resin film”, another feature neither disclosed nor suggested by the prior art of record.

Finally, claims 11 and 12 are patentable at least by reason of their dependency on amended claim 1.

Now that all of the claims are believed to be allowable, the prompt issuance of a Notice of Allowability is hereby earnestly solicited.

Respectfully submitted,

Date: June 17, 2008


Thomas W. Cole
Registration No. 28,290

Customer No. 25570

Roberts Mlotkowski Safran & Cole, P.C.
P.O. Box 10064
McLean, VA 22102
Telephone: (703) 677-3001